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In the Supreme Court of the United States

OCTOBER TERM, 1975

Nos. 75-1602, 75-1612, 75-1613, 75-1614

E. I. DUPONT DE NEMOURS AND COMPANY, ET AL., PETITIONERS

v.

ENVIRONMENTAL PROTECTION AGENCY

ON PETITIONS FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

BRIEF FOR THE ENVIRONMENTAL PROTECTION AGENCY IN OPPOSITION

OPINION BELOW

The opinion of the court of appeals, together with concurring and dissenting opinions, is unofficially reported at 8 E.R.C. 1785, and is reproduced in the Joint Appendix to the petitions.

JURISDICTION

The judgment of the court of appeals was entered on March 19, 1976. The petition in No. 75-1602 was filed on May 3, 1976; the three other petitions were filed on May 5, 1976. This Court's jurisdiction is invoked under 28 U.S.C. 1254(1).

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QUESTIONS PRESENTED

1. Whether Section 211(c)(1)(A) of the Clean Air Act, which authorizes the Administrator of the Environmental Protection Agency to regulate motor vehicle fuel additives, the emissions of which "will endanger the public health or welfare," empowers the Administrator to regulate lead additives upon a determination that they pose a significant risk of harm to the public health, even if it cannot be conclusively proven as a scientific fact that they cause actual harm.

2. Whether the judicial review of the agency rulemaking in this case was adequate.

3. Whether the Administrator's decision to regulate lead additives has a rational basis in the record.

4. Whether on the facts of this case petitioners were afforded adequate notice of and opportunity to comment on certain materials considered by the Administrator in formulating his regulations.

5. Whether the Administrator abused his discretion in deciding to regulate lead additives under Section 211(c)(1)(A) rather than under the provisions of the Clean Air Act authorizing him to establish ambient air quality standards.

STATUTES INVOLVED

The relevant statutes are set forth at pages 3–4 of the petition in No. 75–1602.

STATEMENT

Section 211(c)(1)(A) of the Clean Air Act, as amended, 42 U.S.C. 1857f–6c(c)(1)(A), authorizes the

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Administrator of the Environmental Protection Agency ("EPA") to control or prohibit the use of any motor vehicle fuel or fuel additive, the emission products of which "will endanger the public health or welfare." Based on a review of the medical and scientific evidence received during an informal rulemaking proceeding lasting nearly three years, the Administrator concluded that "lead particle emissions from motor vehicles present a significant risk of harm to the health of urban populations, particularly to the health of city children," and, on December 6, 1973, he accordingly promulgated regulations reducing the use of lead additives in gasoline by 60 percent over a period of five years. 38 Fed. Reg. 33734 (Jt. App. 2).[1] These cases seek review of those regulations.

1. THE ADMINISTRATIVE PROCEEDINGS

On January 30, 1971, the Administrator issued an advance notice of proposed rulemaking announcing that he was considering the regulation of lead additives to gasoline to protect the public health. 36 Fed. Reg. 1486 (Jt. App. 26). On February 23, 1972, having concluded that levels of airborne lead exceeding two micrograms per cubic meter of air were associated with a risk of harm to public health, the Administrator proposed regulations requiring the

[1] "Jt. App." refers to the Joint Appendix to the briefs filed in the court of appeals. "R. Doc." refers to documents contained in the certified index to the record. "NAS Report" refers to *Airborne Lead in Perspective*, a report of the National Academy of Sciences (R. Doc. 14).

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gradual reduction in the lead content of leaded gasoline in order to achieve acceptable air levels of lead throughout the country by 1977. 37 Fed. Reg. 3882 (Jt. App. 23).[2] An extensive evalution of the medical and scientific evidence supporting the regulations was issued simultaneously (Jt. App. 292), comments were invited to be submitted within 90 days, and public hearings were held in three cities. On June 14, 1972, the Administrator reopened the comment period for an additional 30 days to obtain comments on a number of specific scientific and policy issues concerning the health effects of lead. 37 Fed. Reg. 11786 (Jt. App. 20).

Evaluation of the information and comments received led the Administrator to revise his approach to the evaluation of the health effects of automotive lead emissions. He determined that the precise microgram level at which airborne lead creates a risk of harm to public health is difficult if not impossible to identify, and that in considering the problem of human lead levels the cumulative effect and relative signif-

[2] The January 30, 1971 notice also announced that the EPA was considering regulations requiring the sale of lead-free gasoline to protect catalytic converter emission control devices on automobiles. Such regulations were proposed along with the lead-reduction regulations on February 23, 1972, and were promulgated on January 10, 1973. 38 Fed. Reg. 1254. They were upheld in *Amoco Oil Co.* v. *Environmental Protection Agency*, 501 F.2d 722 (C.A.D.C.), and are not at issue here. The use of unleaded fuel in vehicles requiring it is expected to account for most of the 60-percent reduction in lead usage projected to occur under both the lead-free and the lead reduction regulations. 38 Fed. Reg. 33734, 33739–33740 (Jt. App. 7–8).

icance of multiple sources of human lead exposure should be taken into account. On the basis of this reanalysis the Administrator reproposed lead additive regulations on January 10, 1973 (38 Fed. Reg. 1258 (Jt. App. 15)), and issued a second evaluation of the evidence, or "health document," explaining the basis for his conclusions (Jt. App. 158). Comments were requested to be submitted within 60 days, although EPA in fact received and evaluated comments submitted by interested persons, including petitioners, up to the time of the promulgation of the final regulations. All comments were placed in the Agency's public file as they were received.

Shortly after the reproposal the Natural Resources Defense Council ("NRDC") brought an action in the United States Court of Appeals for the District of Columbia Circuit to compel EPA to reach a decision on lead additives forthwith. On April 27, 1973, Judges Tamm and Robb denied NRDC's motion for prehearing conference, summary reversal, or expedition "without prejudice to [NRDC's] renewing that aspect of their motion seeking to compel agency action unreasonably delayed * * * if final action has not been taken within 60 days from the date of this order."[3] On July 3, 1973, EPA advised the court that it expected to announce its decision by August 31.

Although this prediction proved overly optimistic, the preamble to the final regulations, the final health

[3] *Natural Resources Defense Council* v. *Environmental Protection Agency*, No. 72-2233, decided April 27, 1973 (C.A.D.C.).

document, and other technical and economic analyses were substantially complete by October, 1973 (Jt. App. 1502, R. Doc. 486 (preamble); R. Doc. 141 (health document); Jt. App. 1527 (cost and energy impacts)). On October 28, 1973, in response to another motion by NRDC, the court ordered EPA to decide within 30 days whether to issue the lead regulations. EPA sought no further modification or review of this order, and in fact announced its decision on November 28, 1973.

The final regulations were promulgated on December 6, 1973, accompanied by a comprehensive preamble and a final health document reviewing the medical and scientific evidence accumulated throughout the rulemaking. 38 Fed. Reg. 33734 (Jt. App. 1, 27). The final health document differed from the second in two respects: it incorporated the information received during the third comment period and it presented a more extensive discussion of the scientific studies relied upon by the opponents of the regulation.[4] The Administrator's justification for regulating lead additives to protect the public health did not change be-

[4] This expanded discussion of the studies relied upon by opponents of regulation considerably increased the number of references cited in the final document, as noted in Ethyl's petition at page 22.

[5] The Administrator considered and rejected the alternative of setting national ambient air standards for lead under Sections 108 and 109 of the Clean Air Act, 42 U.S.C. 1857c–3 and 1857c–4, as a means to require state or local regulation of lead emissions where necessary, on the grounds that uniform national controls were a more efficient and effective means of regulating gasoline content

tween reproposal and promulgation of the final lead regulations.[5]

2. THE BASIS FOR THE REGULATIONS

The preamble to the regulations (Jt. App. 1) and the final health document (Jt. App. 27), and the summary of those documents set forth in the majority opinion of the court of appeals (pp. 74–97 and Appendices A and B), explain at considerable length the evidentiary basis for the Administrator's regulations. Only the briefest recapitulation is presented here.

Automotive lead emissions are a massive source of lead exposure and the only man-made source not yet subject to control. More than 250,000 tons of lead per year are used in the production of gasoline additives, and motor vehicle emissions contribute more the 90 percent of airborne lead concentrations (Jt. App. 46, 47). According to the United States Public Health Service, blood lead levels in human beings of 80 micrograms of lead per 100 grams of blood (80 ugs./100 gs.) indicate unequivocal lead poisoning possibly resulting in anemia, nerve damage, mental retardation, and even death (Jt. App. 71). Levels of 50–70 ugs. justify immediate evaluation for possible lead poisoning (Jt. App. 71). The health effects of blood lead levels in the 40–60 ugs./100 gs. range re-

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and that a proliferation of state and local controls would be contrary to the intent of Congress and to the expressed preference of the petroleum industry for uniform national requirements (Jt. App. 1937, 1939–1940).

main uncertain, although physiological change is known to occur and several studies have associated anemia and behaviorial disorders in children with elevated blood lead levels in this range (Jt. App. 59–60, 71–73). At levels in excess of 40 micrograms, inhibition of the enzyme ALAD, associated with the formation of red blood cells, is likely to occur (Jt. App. 343), and under the Public Health Service Guidelines blood lead levels exceeding 40 micrograms indicate excessive lead absorption (Jt. App. 71).

The Administrator found that the blood lead levels of many children, particularly those living in urban areas, and of a significant number of adults who are exposed to automobile fumes in an outdoor environment exceed the 40 microgram mark (Jt. App. 143–145, 344, 822; NAS Report, R. Doc. 14, p. 139). He pointed out that because of the multiple sources of human lead exposure, however—such as food, water, air, dust, and leaded paint—the certain identification of the source of lead in any group of individuals has proved to be all but impossible. The Administrator concluded, however, that airborne lead contributes significantly to the human body burden of lead. 38 Fed. Reg. 33734, 33735–33736 (Jt. App. 3–4).

Three kinds of scientific evidence led the Administrator to this conclusion: (1) epidemiological studies showing higher blood lead levels in urban as compared to suburban dwellers, in persons living near roadways, and in persons whose employment exposes them to constantly high air lead levels (such as city police-

men) (Jt. App. 465, 840, 1092, 789); (2) experimental calculations of human lead absorption and intake at various levels of airborne lead, based on knowledge of volumes of air inhaled, ambient lead concentrations, and the rate of deposition in the lung (Jt. App. 86–87, 326, 500); and (3) clinical studies of volunteer subjects exposed to lead in controlled environments (Jt. App. 580, 678, 704). The epidemiological studies provided qualitative evidence of the contribution of airborne lead, while the experimental calculations and clinical studies each indicated that, at airborne lead levels common in American cities, inhaled lead contributes nearly 30 percent of the lead absorbed by the body (Jt. App. 580, 596, 704).[6]

The Administrator acknowledged that none of these methodological approaches produces scientifically unassailable results (Jt. App. 2–3). Taking into account possibilities for misestimate in the three types of studies, however, and weighing all of the other scientific and medical evidence accumulated during the rulemaking proceedings, the Administrator concluded that lead from automobiles presents a significant risk of harm to the public health: harm to adults from inhaling lead in the air, and harm to children both from inhaling lead and from consuming it in dust and dirt.

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[6] The evidence also indicates that children may ingest lead found to exist in high levels in dust and dirt in areas of high motor vehicle activity (the "dustfall hypothesis") (Jt. App. 111–117). Approximately 50 percent of children between the ages of one and three exhibit the tendency to eat nonfood items, including dust and dirt, known as "pica" (NAS Report, R. Doc. 14, p. 133).

The Administrator also concluded that additives that pose a significant risk of harm to the public health "will endanger the public health or welfare" within the meaning of Section 211(c)(1)(A) (Jt. App. 3).[7]

3. THE COURT OF APPEALS' DECISION

A divided panel of the United States Court of Appeals for the District of Columbia Circuit initially set aside the regulations.[8] On rehearing *en banc* after supplemental briefing and reargument, the court upheld the regulations.

The court's opinion carefully considered the meaning of the "will endanger the public health or welfare" standard of Section 211, and thoroughly reviewed both the substantive scientific evidence underlying the regulations and the procedural regularity of the agency proceedings leading to their promulgation. The court held that the Administrator's construction of the statutory language was entitled to great deference, and that there was nothing in the statute or its legislative history to vitiate his con-

[7] The Administrator also determined, based upon the results of economic studies performed by EPA and its contractors, that the cost attributable to the health-based regulations under "worst case assumptions" would be less than one-tenth of a cent per gallon by 1980 and that the increase in crude oil requirements would be less than four-tenths of one percent of projected crude oil demand. EPA projected no further increases in cost by 1985 and a crude oil "penalty" of only one-and-one-half percent. 38 Fed. Reg. 33734, 33739 (J. App. 1527, 1538–1543).

[8] *Ethyl Corp.* v. *Environmental Protection Agency*, 7 ERC 1387 (January 28, 1975).

clusion that the statute is precautionary in nature and authorizes regulation of additives that pose a significant risk of harm to the public health even if actual harm can not be conclusively proven as a matter of scientific fact (Maj. Op. 17, 37). The court also held that the Administrator was correct in his view that, when the record contains evidence of significant risk of harm, but the scientific studies supporting that conclusion are conflicting and the subject is "on the frontiers of scientific knowledge," the question of endangerment becomes in some measure a policy judgment to be made upon an assessment of the risk posed and the likelihood of its occurrence (Maj. Op. 54).

After an exhaustive review of the record, the court held that the Administrator's determination that automotive lead emissions present such a risk has a rational basis in the evidence (Maj. Op. 57–83).

Finally, the court noted that the Administrator had invited comments for three specific periods during the extended rulemaking proceedings, and indeed had accepted comments throughout the entire proceeding; that he had placed in the agency public files all of the evidence that was received and had sent copies of much of the evidence directly to petitioner Ethyl; and that all of the petitioners had had ample notice of and opportunity to comment upon the evidence relied upon by the Administrator in promulgating the regulations (Maj. Op. 97–111). The court concluded that EPA procedures leading to the rulemaking had therefore fully complied with the notice and comment require-

ments of the Administrative Procedure Act (Maj. Op. 109–110).

Judge Wilkey, joined by Judges Tamm and Robb, dissented. Although they generally agreed with the Administrator and the majority that a finding of a significant risk of harm satisfies Section 211(c)(1)(A)'s endangerment standards,[9] they concluded that the statute does not permit regulation unless the Administrator is first able to make a determination, based "purely on the scientific and medical data" (Min. Op. 55), that lead additives actually cause a significant health hazard (Min. Op. 52). They also agreed with the majority opinion as to the scope of review (Min. Op. 57–64), although they concluded upon their evaluation of the underlying evidence that the Administrator's determination to regulate lead additives was arbitrary and capricious (Min. Op. 64–85). Joined by Judge McKinnon, the dissenting judges would have held the procedures leading to the regulations inadequate on the ground that, in their view, the Administrator did not give sufficient notice of and opportunity

[9] *E.g.*, "[o]n reargument the dissenting judges conclude that the disagreement with regard to the legal standard reduces itself to semantics, and while the Administrator did not couch his principal determinations in the language of the statute, the language that he did use, properly interpreted in accordance with the statute, did provide a sufficient standard for his determinations" (Min. Op. 4). See also *id.* at 50–52, 85.

for comment on the evidence upon which he relied in reaching his decision to regulate (Min. Op. 4–50).[10]

ARGUMENT

The decision of the court of appeals is correct and no further review is warranted. There is neither a conflict among the circuits regarding the statutory standard of endangerment to health, nor a plain disagreement of any consequence among the judges of the *en banc* court regarding the proper scope of review. The majority correctly concluded that the Administrator's decision to regulate has a rational basis in the record evidence, and in any event this factual ruling does not merit further consideration by this Court. Similarly, the majority's conclusion that the procedures followed by EPA afforded petitioners a meaningful opportunity to comment upon the regulations was correct and was disputed by the dissent on largely factual grounds peculiar to this case alone. Finally, the Administrator did not abuse his discretion in de-

[10] Judge Bazelon (joined by Judge McGowan), concurring in the majority opinion, wrote that he considered the court to have engaged in a study of the substantive evidence beyond that called for by the court's reviewing function (Bazelon Op. 1–5). Judge Leventhal, who concurred in the majority opinion "without reservation," objected to Judge Bazelon's opinion insofar as it appeared to advocate engaging in no substantive review at all (although Judge Leventhal was not certain that Judge Bazelon actually held such a view) (Leventhal Op. 1–4).

ciding to regulate lead additives under Section 211-(c)(1)(A) rather than to adopt alternative control strategies authorized by the Clean Air Act.

1. The Administrator determined that automotive lead emissions present "a significant risk of harm to the health of urban populations, particularly to the health of city children." 38 Fed. Reg. 33734 (Jt. App. 2). He then construed Section 211(c)(1)(A) to empower him to act, reasoning that additives posing such a risk "will endanger the public health" within the meaning of the statute. All of the judges on the court of appeals apparently agreed with this interpretation of Section 211. They differed over whether, when the subject matter is on the frontiers of scientific knowledge, an assessment of risk of harm to health may encompass predictions based on imperfect evidence and policy judgments, as the majority concluded (Maj. Op. 61–63), or whether risk assessment must be based on precise, quantifiable, and conclusive proof of facts alone, as contended by the dissent (Min. Op. 52).

We submit that the majority view is correct. It is firmly grounded in the terms and intent of Section 211 of the Clean Air Act and is supported by every recent court of appeals' decision construing statutory standards for regulation to protect public health. In *Reserve Mining Co.* v. *Environmental Protection Agency*, 514 F. 2d 492, 528 (C.A. 8) (*en banc*), for instance, the court construed the term "endanger" in

the Federal Water Pollution Act of 1970, 33 U.S.C. 1160(g)(1), as follows:

> In the context of this environmental legislation, we believe that Congress used the term "endangering" in a precautionary or preventive sense, and, therefore, evidence of potential harm as well as actual harm comes within the purview of that term.

Citing the dissent from the initial panel decision in the instant case, the Eighth Circuit unanimously recognized that a determination of endangerment under precautionary statutes may in some circumstances require risk assessment based on inconclusive evidence (514 F. 2d at 507, n. 20):

> [We]note that many of the issues in this case do not involve "historical" facts subject to the ordinary means of judicial resolution. Indeed, a number of the disputes involve conflicting theories and experimental results, about which it would be judicially presumptuous to offer conclusive findings. * * *
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> In such circumstances, the finder of fact must accept certain areas of uncertainty, and the findings themselves cannot extend further than attempting to assess or characterize the strengths and weaknesses of the opposing arguments.

Similarly, decisions reviewing the Secretary of Labor's authority under the Occupational Safety and Health Act, 29 U.S.C. 651 *et seq.*, recognize that fre-

quently the establishment of standards to protect human health will of necessity involve policy judgments. In *Industrial Union Department, AFL-CIO* v. *Hodgson*, 499 F. 2d 467, 474–475 (C.A.D.C.), the court upheld the Secretary's standard for exposure to asbestos dust, stating:

> From extensive and often conflicting evidence, the Secretary in this case made numerous factual determinations. With respect to some of those questions, the evidence was such that the task consisted primarily of evaluating the data and drawing conclusions from it. The court can review that data in the record and determine whether it reflects substantial support for the Secretary's findings. But some of the questions involved in the promulgation of these standards are on the frontiers of scientific knowledge, and consequently as to them insufficient data is presently available to make a fully informed factual determination. Decision making must in that circumstance depend to a greater extent upon policy judgments and less upon purely factual analysis.[18]

The Second Circuit concurs. In *Society of the Plastics Industry, Inc.* v. *Occupational Safety and Health Administration*, 509 F. 2d 1301, certiorari denied, 421 U.S. 992, the court upheld the occupational

[18] Where existing methodology or research in a new area of regulation is deficient, the agency necessarily enjoys broad discretion to attempt to formulate a solution to the best of its ability on the basis of available information. Permian Basin Area Rate Cases, 390 U.S. 747, 811 * * *.

health standards limiting industrial exposure to vinyl chloride to one part per million even though the evidence did not show concrete adverse effects below the 50 ppm level. The court said (509 F. 2d at 1308):

> As in Industrial Union Department, AFL–CIO v. Hodgson, *supra,* the ultimate facts here in dispute are "on the frontiers of scientific knowledge," and, though the factual finger points, it does not conclude. Under the command of OSHA, it remains the duty of the Secretary to act to protect the workingman, and to act even in circumstances where existing methodology or research is deficient. The Secretary, in extrapolating [a particular] study's finding from mouse to man, has chosen to reduce the permissible level to the lowest detectable one. We find no error in this respect.

The majority view below is thus in keeping with the approach followed by each of the circuits to have faced issues involving the administrative decision-making process under regulatory schemes designed to protect the public health in areas where scientific certainty may not always be obtainable. This approach, which recognizes that "step-by-step proof of cause and effect may be impossible" in some cases (Maj. Op. 54), is necessary if the precautionary purpose of statutes such as Section 211 are to be served.

The majority opinion does not, contrary to the suggestion of the dissent (Min. Op. 54), "legitimize the Administrator playing hunches." The majority ob-

served (Maj. Op. 54–55) that, although the Administrator may properly apply his expertise to draw conclusions "from probative preliminary data not yet certifiable as " 'fact,' " his discretion is bounded by the terms of the statute and his conclusions must be rationally justified on the basis of the record evidence.

In determining the risk of injury to the public health created by particular products or practices, it would be a rare case in which the exact degree of risk could be unequivocally established by scientific evidence. The subject involves probabilities, not certainties, and ordinarily it is incapable of exact proof or demonstration. When Congress authorized the Administrator to ban or set limits upon fuel additives that "will endanger the public health," it was legislating in the light of these practical realities of scientific knowledge, and was not imposing upon the Administrator an impossible burden of proof.

In short, disabling the Administrator from acting except in those circumstances where action may be premised solely on proven scientific fact would significantly frustrate the goal of Section 211(c)(1)(A). The court correctly concluded that the Administrator may properly decide whether fuel additives "will endanger the public health" on the basis of policy judgments as well as factual analyses.

2. Petitioners urge that review should be granted

because of an uncertainty they perceive among the members of the court of appeals regarding the proper scope of review of agency rulemaking. The disagreement among the majority as to the extent to which reviewing courts should scrutinize the evidence in scientifically or technologically complex administrative agency cases is also cited in support of the argument that review is warranted here (Dupont Pet. 23–29; Nalco Pet. 15–19; National Petroleum Refiners Association Pet. 18–21).

There is no dispute, however, between the majority and minority over the appropriate scope of review: both agreed that the Administrator's decision must be upheld unless it was "arbitrary and capricious" under Section 10(e)(2)(A) of the Administrative Procedure Act, 5 U.S.C. 706(2)(A) (Maj. Op. 67; Min. Op. 57–58). Although both opinions discussed the effect on the "arbitrary and capricious" standard of this Court's statement in *Citizens to Preserve Overton Park* v. *Volpe,* 401 U.S. 402, 416, that the reviewing court should consider "whether there has been a clear error of judgment" (Maj. Op. 69–70 n. 74; Min. Op. 58–59), the conclusions drawn were substantially identical. Indeed, the dissenting judges themselves observed (Min. Op. 64 n. 139) that "[w]e find our colleagues do not differ materially with us on the standard for review." In short, the majority and minority differed, not as to the proper standard

of review, but only in its application to the particular facts of this case.[11]

Judge Bazelon, joined by Judge McGowan, expressed the view that the court's evaluation of the scientific evidence underlying the Administrator's rulemaking in this case was unnecessarily exhaustive (Bazelon Op. 1–5). But the extent of the disagreement among the majority is too uncertain to warrant review by this Court, assuming that an intracircuit conflict would properly command the Court's attention in any event. Even Judge Leventhal, who wrote separately in support of judges steeping themselves in technical matters in order adequately to discharge their reviewing function (Leventhal Op. 1–4), was uncertain whether Judge Bazelon was advocating a difference in degree of substantive review or a difference in kind.

Moreover, it is difficult to perceive—especially since Judge Leventhal was uncertain about the import of Judge Bazelon's opinion—the basis for petitioner DuPont's assertion (Pet. 12, 24) that Judges Bazelon and McGowan "refused to examine the scientific and technical evidence relied upon by the Administrator in reaching his decision." It does not follow from the statement (Bazelon Op. 4, n. 10) that the exhaustive

[11] Dupont mischaracterizes the majority opinion when it states (DuPont Pet. 12) that it held that "the court was not required to examine carefully the scientific evidence relied on by the Administrator." It is difficult to imagine a more careful review of the evidence than that which both the majority and minority made in this case, and indeed petitioner National Petroleum Refiners Association (Pet. 19) acknowledges that the majority opinion indicates that a " 'close scrutiny of the evidence' " was undertaken.

analysis of the scientific evidence in this case was unnecessary either that Judges Bazelon and McGowan themselves refused to examine the evidence or that (DuPont Pet. 28) "only three of the five majority judges were able to form any conclusion as to the adequacy of the evidence relied upon by the Administrator." In any event, given the thoroughgoing consideration and discussion of the evidence by both the majority and minority opinions, we submit that Judges Bazelon and McGowan were sufficiently familiar with the substantive evidence to allow them adequately to determine whether the Administrator's action was arbitrary and capricious.

Finally, even if the position espoused by Judges Bazelon and McGowan was as starkly at odds with the views of the rest of the court as has been suggested, seven of the nine judges on the court now appear to be in unqualified agreement as to the reviewing court's responsibility. This decision thus settles the law of the circuit, and the court presumably will follow it.

3. On the basis of the explanation contained in the preamble to the regulations and in the accompanying health document (Jt. App. 1 and 27), and for the reasons set out in the opinion of the court (Maj. Op. 66–97), we submit, contrary to the contention of petitioner Nalco (Pet. 19–22), that the record evidence supports the regulations and that accordingly the Administrator was not arbitrary and capricious in promulgating them. This issue, in any event, has now been fully examined twice, first by the panel of the

court of appeals and now by the court of appeals sitting *en banc*. There is no reason for this Court to examine the 30,000–40,000-page administrative record to consider anew the factual question whether the regulations are rationally based upon the evidence.

4. All petitioners argue that they were denied a meaningful opportunity to comment on the regulations in violation of due process and the notice and comment requirements of the Administrative Procedure Act, 5 U.S.C. 553(b) and (c). They contend that the lead regulations were based principally on new information received during the third comment period and unavailable to them, and that the Administrator was required to provide formal notice of his intent to rely on certain comments and studies and to solicit a fourth round of public comments on EPA's position (DuPont Pet. 12–19; Ethyl Pet. 21–27; National Petroleum Refiners Association Pet. 13–17; Nalco Pet. 22–30). As with the claim that the regulations are without rational basis in the record, however, these objections to the procedures followed by the Administrator turn largely on factual issues that were resolved adversely to petitioners below and warrant no further review.

Section 4 of the Administrative Procedure Act requires that notice of a proposed rulemaking be published in the Federal Register and that the notice include "either the terms or substance of the proposed rule or a description of the subjects and issues involved." 5 U.S.C. 553(b). The agency must provide "an opportunity to participate in the rulemaking

through submission of written data, views, or arguments with or without opportunity for oral presentation. After consideration of the relevant matter presented, the agency shall incorporate in the rules adopted a concise general statement of the basis and purpose." 5 U.S.C. 553(c).

In this case EPA not only met but even exceeded these requirements. Although, as the court correctly observed (Maj. Op. 99), Section 4 does not require "new notice whenever the agency responsibility adopts the suggestions of interested parties," EPA nevertheless reproposed the lead regulations to obtain additional comments on the revised health position adopted by the Administrator in response to critical comments and additional information received during the two previous comment periods. Indeed, charged with the statutory duty to consider "all relevant medical and scientific evidence,"[12] the Administrator continued to accept information submitted beyond the expiration of the noticed 60-day period and made every effort to evaluate all of the material received and to incorporate it in the final health document.[13]

The dissent below did not disagree with the court's perception of the governing legal standard under Section 4 (Min. Op. 26). Rather, the dissent was predicated on the factual assertion (Min. Op. 19–20) that the Administrator, upon reviewing the evidence

[12] Section 211(c)(2)(A), 42 U.S.C. 1857f–6c(c)(2)(A).

[13] For example, two studies submitted to the Administrator by petitioner Ethyl Corporation in late October, 1973 were considered and discussed in the final health document (Jt. App. 72–73, 125–126).

and the comments received, did not attempt to defend earlier studies that had been subject to criticism, but instead relied heavily on new studies received during the third comment period indicating that airborne lead contributes significantly to lead exposure in the general population.

We submit that, on the contrary, most of the evidence relied upon by the Administrator was *not* new: a review of the preamble's summary of the evidence relied upon (Jt. App. 1) shows that it refers principally to studies that were available and discussed in the second health document issued with the reproposed regulations. The "new studies" to which the minority referred (Min. Op. 20–23) consisted of a Japanese epidemiological study sponsored by the lead industry's research organization and submitted to EPA in July 1973, certain lead isotope tracer studies, and an additional statistical analysis of an earlier "Seven Cities" study (see Jt. App. 985).

EPA's characterization of the results of the isotope and Japanese studies as "preliminary" (38 Fed. Reg. 33735 (Jt. App. 3)) indicates that only limited reliance was placed on this evidence, and in any event these studies only confirmed the other, principal epidemiological and clinical studies that the Administrator relied upon. Similarly, as the court pointed out (Maj. Op. 104), the facts "vitiate [the minority's] criticism of the Administrator's reliance on" the additional analysis of the Seven Cities study, prepared in response to comments on its statistical methods, since it "merely reconfirmed the validity" of the urban-suburban differences previously cited by

both EPA and the authors of the study themselves (Jt. App. 89; Maj. Op. 103–105).

The summary of evidence relied upon in support of the "dustfall hypothesis" (that children ingest lead fall-out in dust and dirt), itself but a secondary basis for the conclusion that automotive lead emissions contribute to a risk of harm to health (Maj. Op. 88–95), similarly refers mainly to studies that were pointed out in the second health document.[14] 38 Fed. Reg. 33734, 33735–33737 (Jt. App. 3–5). The "new" evidence pertinent to the dustfall hypothesis is summarized in a separate section of the preamble entitled "What new information has become available since reproposal of the regulation and as a result of the additional comment period"? *Id.* at 33737 (Jt. App. 5). It is apparent from the summary that this evidence was evaluated separately and was, again, strictly confirmative of the principal findings.[15] The majority perceived the facts correctly in concluding (Maj. Op. 106–107):

> [T]he Administrator's placement of the discussion of these studies makes clear [that] the

[14] These included evidence as to the high levels of lead inside and outside buildings in urban areas, the prevalence of "pica" in young children, the El Paso study implicating dustfall lead in causing high blood lead levels in children, and the existence of high blood levels in many children with no known exposure to leaded paint (Jt. App. 231–238).

[15] *E.g.*, the Administrator stated that it has been "reaffirmed" that high dust lead levels have been found in children's play areas, that new evidence "reaffirms" that such levels can be caused by automotive lead emissions, that cases of exposure to lead "continue" to be reported from areas in which leaded paint would not be expected to be the predominant factor. 38 Fed. Reg. 33737 (Jt. App. 5).

> studies are not needed or used to support the conclusion that the dustfall hypothesis is reasonable. That conclusion is a sufficient basis for regulation under the statute [for reasons already stated]. * * * These additional studies, which are corroborative of the dustfall hypothesis * * * play no role in the Administrator's decision to regulate.

Moreover, none of the information at issue was "new" in the sense that it had previously been unavailable for public comment and criticism. As the court observed (Maj. Op. 97–100 & n. 99–102), all of the evidence on which the Administrator relied was made available to the public at least three months before the final regulations were issued, and the APA notice and comment requirements are fully satisfied when, as here, the agency placed all the evidence it received in a designated public access file and repeatedly announced the existence and location of the file in the Federal Register.

The dispute between the majority and the dissent, in any event, is at bottom a factual disagreement not warranting further review. The dissenting judges themselves recognized that (Min. Op. 31–32), "there appears to be little, if any, difference in our position on EPA's responsibilities under the APA and our colleagues' position on this subject." Rather, the issue dividing the court was whether opportunity for meaningful comment was afforded in respect of certain information received by EPA subsequent to the third

comment period (Min. Op. 32).[16] Resolution of this issue turns on an assessment of complicated facts peculiar to this case alone.[17]

[16] Similarly, the effect of the court's order of October 28, 1973, directing the Administrator to reach a decision with respect to lead additives within 30 days (see pages 5–6, *supra*), is a factual matter that was resolved adversely to petitioners below. Petitioner DuPont errs (Pet. 15) in asserting that "Two of the requisite members of the majority * * * conceded that the 30-day order may have 'interfered with' deliberate consideration by the agency (Bazelon op. p. 5)." The quoted language, when read in the context of Judge Bazelon's opinion, shows that he was referring to the state of the record, not with the agency's ability to give "deliberate consideration" to the subject before it:

"It is regrettable that EPA did not give the same care to clearly setting forth procedural matters for the record as it gave to substantive matters. It may well be that this court's 30-day order interfered with the opportunity to do so."

[17] Although in the court of appeals petitioners did not assert that they were prejudiced by EPA's public file system, petitioner Nalco now complains of the filing system's failure to disclose the dates when certain documents were received, and contends that the court improperly relied upon a letter dated September 26, 1975, from agency counsel which set forth, based on other agency records, the approximate dates when certain documents were in fact received and transmitted to the file. The failure of the filing system to record dates of entry does not vitiate EPA's compliance with the notice requirements of the APA. See Maj. Op. 97–98 n. 99; 100–101 n. 102; 102 n. 106. The September 26, 1975 letter from agency counsel was written in response to a request from the court; copies were sent to all parties of record (including Nalco) (Nalco Pet. 26), and no party commented in response. (Nalco's statement (Pet. 26) that it received this letter only after a specific request is incorrect.)

EPA counsel did send two letters to the court (again in response to court request) that were not served upon opposing counsel (Nalco Pet. B1, B8). While the better practice would have been to have served opposing counsel, the substance of the communications were not prejudicial to petitioners or otherwise improper.

5. Petitioners DuPont (Pet. 3 n. 2) and National Petroleum Refiners Association (Pet. 21–23) claim that the Administrator abused his discretion in deciding to regulate lead additives under Section 211(c)(1)(A) rather than to establish ambient air quality standards for lead under Section 109. We submit, on the contrary, that the Administrator's decision in this regard is both reasonable and in harmony with the terms and legislative history of the Clean Air Act.

The Administrator chose to set national fuel standards for lead gasoline because this technique provides the most efficient and effective means of accomplishing a reduction in lead emissions. It is easier for industry to comply with a single standard rather than with the proliferation of differing state or regional regulations that would likely arise under ambient air quality standards. Moreover, federal controls at the refinery level are more efficient than state or local controls aimed at thousands of fuel distributors and retailers.

The Administrator was also aware that the states were having difficulty implementing the six ambient air quality standards that have already been promulgated, and considered it desirable to avoid giving them another major regulatory task when more effective alternatives were available (see EPA's supplemental reply brief in the court of appeals at 20). Moreover, the oil industry itself largely prefers a uniform nationwide standard instead of a patchwork of different state and local standards (see *id.* at 23–25). Finally, Congress enacted Section 211(c)(1)(A)

with the expectation that control or prohibition of lead additives in gasoline might be necessary.[18] That provision specifically authorizes EPA to impose such standards on a nationwide basis, and it contains no mention whatever of Section 109.

The court of appeals correctly concluded that the Administrator did not abuse his discretion in determining that the establishment of uniform nationwide standards for lead additives was preferable to a regulatory scheme subject to variations among state and local jurisdictions.

CONCLUSION

The petitions for a writ of certiorari should be denied.

Respectfully submitted.

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MAY 1976.

[18] See, *e.g.*, S. Rep. No. 91-1196, 91st Cong., 2d Sess. 33 (1970); 116 Cong. Rec. 19229 (1970) (remarks of Representative Rogers); 116 Cong. Rec. 32920 (1970) (remarks of Senator Baker).

U.S. GOVERNMENT PRINTING OFFICE: 1976